K040614

APR - 7 2004

510 (k) SUMMARY

CONTACT: Larry L. Blosser

DATE PREPARED: January 22, 2004

TRADE OR PROPRIETARY NAME: BlueWand™ Dental Curing Wand System

CLASSIFICATION NAME: visible light cure for polymerization

PREDICATE DEVICES:

L.E. Demetron 1	K021797

DEVICE DESCRIPTION:

The BlueWand™ LED Dental Curing Light is a cordless battery-powered unit designed for curing visible light cured (VLC) materials whose initiators are sensitive to light in the 440-480 nm wavelength region of the visible spectrum. The light is based on LED (light emitting diodes) technology for light generation.

The BlueWand™ LED Dental Curing Light System includes:

- Surgical stainless steel handpiece with an LED and control electronics with rechargeable battery
- Transformer to supply wall power to the base unit
- Base unit- charges battery and stores handpiece when not in use

The BlueWand™ has 6 standard curing modes, consisting of 10, 20 and 30 second durations, and operational from two settings: Manual Setting and Automatic Setting. ("Touch less – ON" function). The Modes are10s, 20s, and 30s, a ramp, and two "30% reduced power" modes for 20s and 30s.

INTENDED USE:

Curing camphorquinone-based visible light cured (VLC) materials

TECHNOLOGICAL CHARACTERISTICS

The BlueWand™ LED Dental Curing Light System is substantially equivalent to K021797 in intended use, operation, including the range of light emitted, curing time, and cooling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 7 2004

Mr. Larry L. Blosser
President
J.L. Blosser, Incorporated
22 North Main
Liberty, Missouri 64068

Re: K040614
Trade/Device Name: BlueWand™ LED Curing Wand System
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: II
Product Code: EBZ
Dated: January 22, 2004
Received: March 11, 2004

Dear Mr. Blosser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

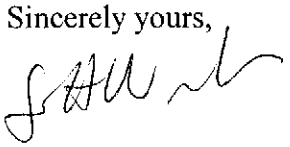
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040614

Device Name: BlueWand™ LED Dental Curing Wand System

Indications for Use:

The BlueWand™ LED Dental Curing Wand System is a cordless light intended for polymerization of visible light cured materials containing camphorquinone.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR Part 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert S. Beer, DDS for Dr. S. Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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